1305. Misbranding of Rudy's Pile Suppository. U. S. v. 36 Packages of Rudy's Pile Suppository. Default decree of condemnation and destruction. (F. D. C. No. 12361. Sample No. 79374-F.)

On May 11, 1944, the United States attorney for the Eastern District of Virginia filed a libel against 36 packages of the above-mentioned product at Norfolk, Va., alleging that the article had been shipped on or about February 14, 1944, by the Martin Rudy Estate, from Lancaster, Pa.

Examination of samples showed that the article consisted essentially of lead carbonate 0.25 grain, tannic acid, creosote, and iodoform in a sup-

pository base.

The article was alleged to be misbranded (1) in that the statement in the labeling, "Tends to relieve the discomforts of Piles (Bleeding \* \* \* Protruding)," was false and misleading since the article would not constitute a safe and effective treatment for the discomfort of bleeding and protruding piles; (2) in that its labeling failed to bear adequate warnings against its use in the case of bleeding piles; and (3) in that it was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the label.

On July 14, 1944, no claimant having appeared, judgment of condemnation

was entered and the product was ordered destroyed.

## DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS\*

1306. Adulteration and misbranding of Dr. Hubbels Formula for Dental Hygiene. U. S. v. Hubbel Products Corporation. Plea of guilty. Fine, \$50. (F. D. C. No. 12597. Sample No. 52281-F.)

On November 6, 1944, the United States attorney for the District of Massachusetts filed an information against the Hubbel Products Corporation, Boston, Mass., alleging shipment of a quantity of the above-named product from the State of Massachusetts into the State of Maine, on or about March 11, 1944.

The article was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess, since it was represented as containing 8 grains of chloral hydrate to the fluid ounce, whereas it contained approximately 14 grains of chloral hydrate to the fluid ounce.

It was alleged to be misbranded (1) in that the statement on its label, "Chloral Hydrate 8 grs. to Fluid Oz.," was false and misleading; (2) in that its label bore no statement of the quantity of the contents; (3) in that its labeling bore no directions for use; and (4) in that it was a drug for use by man, and it contained chloral hydrate, a derivative of chloral, which derivative, by regulations, has been designated as habit-forming, but the label of the article did not bear the name and quantity or proportion of the derivative and, in juxtaposition therewith, the statement "Warning—May be habit-forming."

On December 27, 1944, a plea of guilty having been entered on behalf of the corporation, the court imposed a fine of \$25 on each of 2 counts, a total

fine of \$50.

1307. Misbranding of Fentone Compound. U. S. v. 31 Packages of Fentone Compound.

Default decree of condemnation and destruction. (F. D. C. No. 12297. Sample No. 41524-F.)

On May 19, 1944, the United States attorney for the Southern District of Mississippi filed a libel against 31 packages of Fentone Compound at Jackson, Miss., alleging that the article had been shipped on or about August 5 and September 25, 1943, from Paris, Tenn., by the Fentone Medicine Co.

Examination showed that the article consisted essentially of water; Epsom salt; small proportions of sodium salicylate; iron, ammonium, and potassium compounds, including carbonates and phosphates; saccharin; oil of cinnamon;

and a red coloring matter.

The article was alleged to be misbranded because of false and misleading statements on its label and in an accompanying circular entitled, "Is Intestinal Stasis Spreading Poisons Throughout Your System Contaminating the Blood-Stream, Liver and Kidneys?", regarding the efficacy of the article in the treatment of liver and kidney disorders, high blood pressure, rheumatism,

<sup>\*</sup>See also Nos. 1304, 1305.